

10 Rec'd PTO/PTC

19 JAN 2005

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q83534

Andrew Lennard LEWIS, et al.

Appln. No.: 10/506,805

Group Art Unit: not yet assigned

Confirmation No.: not yet assigned

Examiner: not yet assigned

Filed: September 7, 2004

For: DRUG CARRIERS COMPRISING AMPHIPHILIC BLOCK COPOLYMERS

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. §§ 1.97 and 1.98**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. § 1.56, Applicant hereby notifies the U.S. Patent and Trademark Office of the documents which are listed on the attached PTO/SB/08 A & B (modified) form and/or listed herein and which the Examiner may deem material to patentability of the claims of the above-identified application.

One copy of each of the listed documents is submitted herewith., except for the U.S. patent. In addition, a copy of the International Search Report which identifies items 1-3 listed below, is also enclosed.

1. U.S. Patent No. 5,846,558 issued December 8, 1998, to Nielsen et al.
2. World Patent No. 99/43343 A1, published September 2, 1999.
3. World Patent No. 02/28929 A1, published April 11, 2002.

Andrew Lennard LEWIS, et al.  
U.S. Appln. No. 10/506,805  
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4. V. Alakhov et al., "Block Copolymer-Based Formulations of Doxorubicin Effective Against Drug Resistant Tumors", *Biomedical Polymers and Polymer Therapeutics*, (2001), pp. 121-137.
5. V. Alakhov et al., "Block copolymer-based formulation of doxorubicin. From cell screen to clinical trials", *Colloids & Surfaces B: Biointerfaces*, Vol. 16 (1-4), (1999), pp. 113-134.
6. E.J. Ashford et al., "First example of the atom transfer radical polymerisation of an acidic monomer: direct synthesis of methacrylic acid copolymers in aqueous media", *Chem. Commun.*, (1999), pp. 1285-1286.
7. I. Astafieva et al., "Critical Micellization Phenomena in Block Polyelectrolyte Solutions", *Macromolecules*, Vol. 26, (1993), pp. 7339-7352.
8. V. Bütün et al., "Synthesis and aqueous solution properties of near-monodisperse tertiary amine methacrylate homopolymers and diblock copolymers", *Polymer*, Vol. 42, (2001), pp. 593-6008.
9. T. Inoue et al., "An AB block copolymer of oligo(methacrylate) and poly(acrylic acid) for micellar delivery of hydrophobic drugs", *Journal of Controlled Release*, Vol. 51, (1998), pp. 221-229.
10. M. Jones et al., "Polymeric micelles - a new generation of colloidal drug carriers", *European Journal of Pharmaceutics and Biopharmaceutics*, Vol. 48, (1999), pp. 101-111.
11. A. Lee et al., "Characterizing the Structure of pH Dependent Polyelectrolyte Block Copolymer Micelles", *Macromolecules*, Vol. 32, (1999), pp. 4302-4310.

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12. M. Wilhelm et al., "Poly(styrene-ethylene oxide) block copolymer micelle formation in water: A fluorescence probe study", *Macromolecules*, Vol. 24, (1991), 1033-1040.

The present Information Disclosure Statement is being filed: (1) No later than three months from the application's filing date; (2) Before the mailing date of the first Office Action on the merits (whichever is later); or (3) Before the mailing date of the first Office Action after filing a request for continued examination (RCE) under §1.114, and therefore, no Statement under 37 C.F.R. § 1.97(e) or fee under 37 C.F.R. § 1.17(p) is required.

The submission of the listed documents is not intended as an admission that any such document constitutes prior art against the claims of the present application. Applicant does not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account. A duplicate copy of this paper is attached.

Respectfully submitted,

  
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John T. Callahan  
Registration No. 32,607

SUGHRUE MION, PLLC  
Telephone: (202) 293-7060  
Facsimile: (202) 293-7860

WASHINGTON OFFICE

**23373**

CUSTOMER NUMBER

Date: January 19, 2005

Substitute for Form 1449 A & B/PTO  <b><u>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</u></b>  (use as many sheets as necessary)				<i>Complete if Known</i>	
				Application Number	10/506,805
				Confirmation Number	not yet assigned
				Filing Date	September 7, 2004
				First Named Inventor	Andrew Lennard LEWIS
				Art Unit	not yet assigned
				Examiner Name	not yet assigned
Sheet	1	of	1	Attorney Docket Number	Q83534

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		Number	Kind Code <sup>2</sup> (if known)		
		US 5,846,558	A	12/08/1998	Nielsen et al.
		US			
		US			

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Translation <sup>6</sup>
		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)			
		WO	99/43343	A1	09/02/1999	Supratek Pharma Inc.	
		WO	02/28929	A1	04/11/2002	Biocompatibles Ltd.	

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city, and/or country where published.	Translation <sup>6</sup>	
		V. Alakhov et al., "Block Copolymer-Based Formulations of Doxorubicin Effective Against Drug Resistant Tumors", Biomedical Polymers and Polymer Therapeutics, (2001), pp. 121-137.		
		V. Alakhov et al., "Block copolymer-based formulation of doxorubicin. From cell screen to clinical trials", Colloids & Surfaces B: Biointerfaces, Vol. 16 (1-4), (1999), pp. 113-134.		
		E.J. Ashford et al., "First example of the atom transfer radical polymerisation of an acidic monomer: direct synthesis of methacrylic acid copolymers in aqueous media", Chem. Commun., (1999), pp. 1285-1286.		
		V. Bütün et al., "Synthesis and aqueous solution properties of near-monodisperse tertiary amine methacrylate homopolymers and diblock copolymers", Polymer, Vol. 42, (2001), pp. 593-6008.		
		I. Astafieva et al., "Critical Micellization Phenomena in Block Polyelectrolyte Solutions", Macromolecules, Vol. 26, (1993), pp. 7339-7352.		
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		T. Inoue et al., "An AB block copolymer of oligo(methacrylate) and poly(acrylic acid) for micellar delivery of hydrophobic drugs", Journal of Controlled Release, Vol. 51, (1998), pp. 221-229.		
		M. Jones et al., Polymeric micelles - a new generation of colloidal drug carriers", European Journal of Pharmaceutics and Biopharmaceutics", Vol. 48, (1999), pp. 101-111.		
		A. Lee et al., "Characterizing the Structure of pH Dependent Polyelectrolyte Block Copolymer Micelles", Macromolecules, Vol. 32, (1999), pp. 4302-4310.		
		M. Wilhelm et al., "Poly(styrene-ethylene oxide) block copolymer micelle formation in water: A fluorescence probe study", Macromolecules, Vol. 24, (1991), 1033-1040.		

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kind Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov), MPEP 901.04 or in the comment box of this document. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to indicate here if English language Translation is attached.